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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. 11/24/2003 Melvin Rich 33345/US/3 5207 10/720,957 EXAMINER 7590 04/08/2005 Scott D. Rothenberger SPEAR, JAMES M DORSEY & WHITNEY LLP PAPER NUMBER ART UNIT Intellectual Property Department 50 South Sixth Street, Suite 1500 1618 Minneapolis, MN 55402-1498 **DATE MAILED: 04/08/2005**

Please find below and/or attached an Office communication concerning this application or proceeding.

OIPE OF		
anns #	Application No.	Applicant(s)
NIE 2 2 2005	10/720,957	RICH ET AL.
Office Action Summary	Examiner	Art Unit
3 TRAUS	James M. Spear	1615
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
 Responsive to communication(s) filed on <u>26 October 2004</u>. This action is FINAL. 2b) ☐ This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 		
Disposition of Claims		
4) Claim(s) 1-24 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-24 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or		
Application Papers		
9) The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list of	have been received. have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No ed in this National Stage
	9	d. ames) M. Spean
		PRIMARY EXAMINER
Attachment(s)	_	AU1615
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da	
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		atent Application (PTO-152)
S. Patent and Trademark Office	Non Cum.	t of Danie No (Mail Date 04022005

Art Unit: 1615

The amendment filed 26 October 2004 has been entered.

After further review and consideration it has been determined that the following rejection is required.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 and 20 of U.S. Patent No. 6,716,451 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims may differ in scope the dosage formulations do not constitute a patentable distinction. It would have been obvious to place any

Application/Control Number: 10/720,957

Art Unit: 1615

of the particular formulations of the patent claims in capsules for convenience and ease of administration.

- 3. Claims 1-24 are rejected.
- 4. Claim 25 has been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on

Application/Control Number: 10/720,957

Art Unit: 1615

Page 4

access to the Private PAIR system, contact the Electronic Business Center

(EBC) at 866-217-9197 (toll-free).

James M. Spear
James M Spear
Primary Examiner
Art Unit 1615

April 2, 2005